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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,222	12/19/2001	Jerry Pelletier	073406-0701	4998

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EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 10/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/025,222	PELLETIER ET AL.	
	Examiner	Art Unit	
	David J Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *66,71,72,86-88,91 and 105-108* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *88* is/are allowed.

6)☒ Claim(s) *66,71,72,86,87,91 and 106-108* is/are rejected.

7)☒ Claim(s) *105* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *8/24/04; 8/31/04* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] Claims 66, 71-72, 86-88, 91, and 105-108 are pending in the application.

[2] Applicants' amendment to the claims, filed September 01, 2004, 2004, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.

[3] Applicants' arguments filed on September 01, 2004 have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

[4] The text of those sections of Title 35, U.S. Code not included in the instant action can be found in a prior Office action.

Claim Objections

[5] Applicant is advised that should claim 71 be found allowable, claim 106 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

[6] Claim 88 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 105. When two claims in an application are duplicates or else are so close in

content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112, First Paragraph

[7] The written description rejection of claim 72 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record as set forth in item [13] of the Office action mailed June 01, 2004 and item [13] of the Office action mailed January 05, 2004 and for the reasons stated below.

RESPONSE TO ARGUMENTS: Applicants arguments are addressed only to the extent they apply to claim 72. Applicants argue the polypeptide of the composition of claim 72 is limited by structure to those comprising SEQ ID NO:6 and by function to those that bind to a polypeptide comprising SEQ ID NO:4. Applicants argue the genus of polypeptides comprising SEQ ID NO:6 of the composition of claim 72 is limited to a small number of structurally and functionally narrow divergent species. Applicants' arguments are not found persuasive.

The examiner maintains the position that the genus of polypeptides comprising SEQ ID NO:6 of the composition of claim 72 encompass species that are widely variant. The court in *UC California v. Eli Lilly* (CAFC) 43 USPQ2d 1398 (1997) stated that "description of genus of cDNAs may be achieved by means of recitation of representative number of cDNAs... ...or by recitation of structural features which are common to members of genus and constitute substantial portion of genus." The

examiner acknowledges that the species of polypeptides all comprise SEQ ID NO:6 and have the ability to bind SEQ ID NO:4. However, the genus encompasses species that are widely variant with respect to their structures. For example, the polypeptide of O'Donnell et al. (cited in a previous Office action) comprises SEQ ID NO:6, however, as acknowledged by applicants, the structure of the polypeptide of O'Donnell et al. "shows many differences" with respect to structure as compared to the polypeptide of SEQ ID NO:2. In this case, the genus encompasses all species of polypeptides that comprise SEQ ID NO:6, having SEQ ID NO:6 and any additional structural features. As such, the single representative species of SEQ ID NO:2 fails to represent all species encompassed by the genus. Also, it is noted that amino acids 561-599 of SEQ ID NO:2, *i.e.,* SEQ ID NO:6, is a only a minimal portion of the representative polypeptide of SEQ ID NO:2, which is 599 amino acids in length, and consequently this fragment of SEQ ID NO:2 fails to constitute a substantial portion of the genus of claimed polypeptides comprising SEQ ID NO:6 of the composition of claim 72.

[8] The scope of enablement rejection of claims 66, 71-72, 86-87, 91, and 106-108 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record as set forth in item [14] of the Office action mailed June 01, 2004 and item [14] of the Office action mailed January 05, 2004 and for the reasons stated below.

RESPONSE TO ARGUMENTS: Applicants argue that, given the state of the art at the time of the invention in view of the disclosure, the scope of claimed polypeptides is fully enabled by the specification. Applicants argue that amino acids 561-599 of SEQ ID NO:2 is the minimal region necessary for binding to SEQ ID NO:4 and that various

fusion proteins comprising this and other fragments have been shown to bind SEQ ID NO:4. Applicants argue that without proof to the contrary, it is reasonable to assume that any polypeptide comprising SEQ ID NO:6 would bind SEQ ID NO:4. Addressing claim 72, applicants argue the claim is limited to two specific polypeptides which are defined by structure and function, noting that the only essential function is mutual binding. Applicants argue the genus of polypeptides comprising SEQ ID NO:6 as recited in claim 72 must bind SEQ ID NO:4 and it would be "legally improper" to reject claim 72 on the basis that the specification fails to disclose polypeptides that are not claimed. Applicants' arguments are not found persuasive.

The examiner maintains the position that the specification, while being enabling for the isolated polypeptide of SEQ ID NO:2, does not reasonably provide enablement for the full scope of claimed polypeptides. The specification discloses that the interaction of a bacteriophage polypeptide, SEQ ID NO:4, with SEQ ID NO:2 has an inhibitory effect on the growth of *S. aureus* (*e.g.,* pp. 96-97). Applicants have allegedly identified amino acids 561-599 of the *S. aureus* polypeptide of SEQ ID NO:2 as being required for binding of SEQ ID NO:2 to SEQ ID NO:4. Based on these and other findings, the specification asserts the utility of the claimed invention is to identify agents that bind to the *S. aureus* polypeptide of SEQ ID NO:2 in order to identify potential biological agents that may have therapeutic use (p. 109).

First, it is noted that the polypeptides of claims 91 and 107-108 are not limited to those that bind to SEQ ID NO:4 and based on the disclosure, which asserts the utility of the claimed polypeptides as being used for identifying binding agents, it is not clear as

to how a skilled artisan uses those polypeptides that do not have the ability to bind SEQ ID NO:4. Second, it is noted that claims 86-87, 91, and 107-108 are not limited to polypeptides comprising the required interaction domain of SEQ ID NO:2, *i.e.*, amino acids 561-599 of SEQ ID NO:2 and the specification provides no guidance as to amino acids of the domain of SEQ ID NO:2 that are required for binding to SEQ ID NO:4 that can be altered by substitution, addition, deletion, or insertion (as encompassed by the claims) with an expectation of maintaining the ability to bind to SEQ ID NO:4 and it is highly unpredictable as to which alterations will have an adverse affect on binding to SEQ ID NO:4 as evidenced by Branden (cited in a previous Office action). Thus, one of skill in the art is left to alter the sequence of SEQ ID NO:2 for those polypeptides that maintain the ability to bind to SEQ ID NO:4. Such experimentation is not routine in the art.

Even assuming *arguendo* such experimentation was routine, it appears that the fragment of SEQ ID NO:2 which interacts with SEQ ID NO:4 is at the C-terminus of SEQ ID NO:2 (Figure 10), which one of skill in the art would recognize as likely being exposed at the surface of the polypeptide, *i.e.,* not buried within the core of the protein. Thus, one would expect that N-terminal fusions of SEQ ID NO:6 with, *e.g.*, a GST fusion moiety, would likely bind to SEQ ID NO:4 as the fragment of SEQ ID NO:6 would also be expected to be exposed at the surface of the fusion protein. However, there is no evidence of record that would suggest that when the recited fragments of SEQ ID NO:2 are internalized within a polypeptide sequence that such polypeptides also have the ability to bind to SEQ ID NO:4 as the resulting proteins may take on conformations that

inhibit binding of the interaction domain of amino acids 561-599 of SEQ ID NO:2 with SEQ ID NO:4. Thus, it is highly unpredictable as to whether all polypeptides *comprising* the recited fragments of SEQ ID NO:2 would bind to SEQ ID NO:4. Even assuming *arguendo* all the claimed polypeptides have the ability to bind to SEQ ID NO:4, it is noted that the evidence of record indicates that the fragments of SEQ ID NO:2 bind to SEQ ID NO:4, not polypeptides *comprising* SEQ ID NO:4. The specification fails to identify the region of SEQ ID NO:4 that interacts with SEQ ID NO:2 and it is just as likely that the region of SEQ ID NO:4 that interacts with SEQ ID NO:2 is also at the N- or C-terminus of SEQ ID NO:4 and exposed at the surface of the protein. Thus, if SEQ ID NO:4 were internalized within a polypeptide, it is highly unpredictable as to whether the claimed polypeptide would interact with a polypeptide *comprising* SEQ ID NO:4 as a polypeptide *comprising* SEQ ID NO:4 may alter the conformation of SEQ ID NO:4 such that it no longer binds to the interaction domain of SEQ ID NO:2. Such unpredictability is evidenced by Colman et al. (*Res Immun* 145:33-36), which teaches that "[s]ingle amino acid changes within the interface of an antibody-antigen complex... ...can effectively abolish the interaction entirely" (page 33, right column). The teachings of Colman et al. are also relevant to the unpredictability of the effects of altering the sequence of SEQ ID NO:2 with an expectation that the altered polypeptide will have the ability to bind to SEQ ID NO:4 as discussed above. Furthermore, Abaza et al. (*J Protein Chem* 11:433-444) teaches that alterations outside of the boundaries of an antigenic site can significantly affect antibody binding (page 443, right column to page 444, left column). While it is acknowledged that these references do not address the interaction of SEQ ID NO:2 and

4 specifically, it is noted that the interaction of an antibody with its cognate antigen is a protein-protein interaction and thus, the teachings of Colman et al. and Abaza et al. are applicable. Even assuming *arguendo* all polypeptides comprising amino acids 229-599, 380-599, or 561-599 of SEQ ID NO:2 have the ability to bind all polypeptides comprising SEQ ID NO:4, there is no evidence of record that would indicate that this minimal binding domain has the ability to inhibit *S. aureus* cell growth and it is unclear from the specification as to the utility of those polypeptides that bind to SEQ ID NO:4, but do not inhibit the growth of *S. aureus*. As such, one of skill must make all polypeptides as broadly encompassed by the claims, screen those that have the ability to bind to SEQ ID NO:4 and further screen for those polypeptides that have the ability to inhibit the growth of *S. aureus.* At least for the reasons of record and the reasons stated above, the experimentation required to make and use all polypeptides or compositions comprising polypeptides as broadly encompassed by the claims is not routine.

Claim Rejections - 35 USC § 102

[9] The rejection of claim(s) 66-71, 87, and 91 under 35 U.S.C. 102(b) as being anticipated by O'Donnell et al. as set forth at item [15] of the Office action mailed June 01, 2004, is withdrawn. The polypeptide of O'Donnell et al. is neither 95% identical or 97% similar to SEQ ID NO:2 over the *entire length* of SEQ ID NO:2. See Appendix II of applicants' response.

Claim Rejections - 35 USC § 103

[10] The rejection of claim(s) 66-71, 84-85, 87, and 89-91 under 35 U.S.C. 103(a) as being unpatentable over Benton et al. in view of Burgett et al. as set forth at item [17] of the Office action mailed June 01, 2004, is withdrawn. The polypeptide encoded by the nucleic acid of Benton et al. has a number of unidentified nucleotides and gaps between the coding sequence of the nucleic acid of Benton et al. and SEQ ID NO:2. As such, a skilled artisan would not have a reasonable expectation of success that the nucleic acid of Benton et al. would encode the polypeptide of SEQ ID NO:2. Moreover, the polypeptide encoded by the nucleic acid of Benton et al. is neither 95% identical nor 97% similar to SEQ ID NO:2 (see Appendix B of the Office action mailed June 1, 2004).

Conclusion

[11] Status of the claims:

- Claims 66, 71-72, 86-88, 91, and 105-108 are pending.
- Claim 88 appears to be in condition for allowance.
- Claim 105 is objected to.
- Claims 66, 71-72, 86-87, 91, and 106-108 are rejected.
- Claims 66, 71-72, 86-87, 91, and 106-108 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 1st paragraph, set forth in this Office action.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:30 am to 4:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

10-25-04

David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652